IN-VITRO AND CLINICAL MORCELLATOR FUNCTIONALITY ASSESSMENT

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ABSTRACT
Morcellator functionality information is relatively limited in literature and mainly restricted to general clinical data. No specific parameters related to morcellator working principles have been reported, making a surgeons choice to use a specific device mostly based on past experience and potential risks vs. benefits. Gaining insight into the morcellation time, morcellator speed, the number of tissue strips removed at a certain uterus weight and the amount of debris created by the morcellation process, can aid in the assessment of the procedure. This research evaluates these criteria both in-vitro and in clinical practice for a morcellator based on the electromechanical tissue peeling principle. Additionally, time-action analyses are performed to gain insight into the time division of the separate phases inherent to the morcellation procedure. Concluded is that the morcellation rates found in-vitro and from gynaecological procedures are different, but still allow for working principle comparison and insight into the functional speed of the instrument combined with the surgeons experience. Morcellation speed is found to increase with larger uteri, showing better instrument functioning speed at larger tissue masses. Time gained with respect to optimal functioning of the instrument is offset by time lost due to longer inspection and irrigation time necessary for debris removal after the morcellation procedure. Time-action analyses show an approximate 80% downtime of the morcellator both in test setup and in clinical practice, displaying the room for improvement of the instrument.

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NOMENCLATURE

IMR Instrument Morcellation Rate (g/min). Morcellator functioning speed determined from in-vitro obtained data.

PMR Procedure Morcellation Rate (g/min). Morcellator functioning speed determined from data collected at hysterectomy procedures involving morcellation.

MCR Morcellator Cutting Rate (g/min). Effective morcellator cutting speed determined by excluding tissue manipulation and depositing phases in the morcellation process.

\( f_{\text{morcell}} \) The sum of time spend morcellating and afterwards inspecting and irrigating the abdomen for debris, divided by the full procedure time.

\( f_{1-3} \) Time found for a specific time-action analysis phase (1-3) divided by morcellation time.

INTRODUCTION
The use of a morcellator has become standard practice in gynaecology for the partial or total removal of the uterus at hysterectomies. As such, various morcellators exist, as Miller discussed in 2001 [1], and over the years several different working principles have been used. In literature, these instruments have been mainly assessed on the basis of operation time, blood loss, recuperation time, and other general clinical parameters, but rarely is the morcellation procedure itself analyzed, and never have more than two morcellators been compared at the same time. For example, Erian et al. evaluated the difference between the use of a reusable versus disposable electromechani-
morcellation instruments in 2007 [2], and observed significant differences in operative time, estimated blood loss and length of postoperative hospital stay, all in favor of the disposable morcellator. Furthermore, in 2008, they reported on the efficacy of laparoscopic subtotal hysterectomy (LSH) in the management of menorrhagia [3]. They showed only a weak correlation between uterine size and surgery duration, which they attributed to the duration of morcellation, and also found that blood loss was not correlated with uterine size, which reflected the operator’s experience and the quality of the used technology. Martinez-Zamora et al., 2009 [4], performed an equal study, comparing a reusable and a disposable morcellator, and also judged in favor of the disposable instrument (which can be explained on account of difference in morcellator working principles, as explained by Arkenbout et al. [5]). Yet Zullo et al., 2010 [6] found in an equal study with two morcellators based on the same motor peeling working principle, contrary to Erian et al. and Martinez-Zamora et al. no differences between the morcellators except in handling score.

Beside morcellation instrument comparisons, one can also look at how such an instrument functions with respect to patient specific variables (e.g. uterine weight, blood loss, BMI, etc.) and ergonomics. For example, Chang et al., 2008 [7], studied the presence of specific problems in laparoscopically assisted vaginal hysterectomies (LAVH) for certain weight of bulky uteri and the strategies to overcome them. It was concluded that by using various combinations of special strategies, such as laparoscopic and transvaginal volume reduction techniques (e.g. manual bisection and electromechanical morcellation), most experienced gynecologic surgeons could conduct LAVH for most large uteri with minimal rates of complications and conversion to laparotomy, thereby showing the increased value of intra-abdominal uterus morcellation for hysterectomy procedures. Even at Single Port Access Laparoscopic-Assisted Vaginal Hysterectomies (SPA-LAVH), morcellation can be successfully applied for large uterine masses (> 500g) [8], though longer operative time and more blood loss might be anticipated when handling an extremely large uterus (> 900g).

These studies are very useful for assessing and/ or substantiating the choice for or against the use of a morcellator with respect to safety and patient specific variables, but lack objective parameters to allow accurate comparison between morcellators from different studies. Therefore, in a previous literature study the varying instruments available on the market have been cataloged and identified on the basis of their working mechanisms, i.e. the way in which they facilitate tissue removal and transport out of the patient [5]. Moreover, they have been compared on the basis of their Procedure Morcellation Rates (PMR), but it was concluded that even though it appeared that the most current working principle, i.e. tissue peeling with a motorized rotating cutting blade (short: motor peeling), is the fastest, lack of reliable data prevents one to make any conclusive statements. As a result, a data-gathering protocol was proposed for objective morcellator analysis [9].

This article uses the protocol to obtain morcellation data both in-vitro and from actual hysterectomy procedures to demonstrate the functionality of the most commonly used morcellation working principle (i.e. motor peeling). Additionally, insight is gained into the advantages and disadvantages of morcellation.

**MATERIALS AND METHODS**

A test setup was used, consisting of a minimally invasive boxtrainer with two lateral and two median trocar entry points, laparoscope and screen, and a Gynecare Morcellex (Ethicon, Johnson & Johnson) with MD0100 Motor Drive Unit. Two experienced gynaecologists each did five test sessions with the Morcellex in the test setup, morcellating a boiled porcine heart (the choice for this tissue model is briefly discussed in the next subsection). The test sessions were performed over the course of several days (to prevent the tests from becoming a tedious routine) and recorded (with laparoscopic and external camera) for video playback, enabling time-action analysis. Data was additionally gathered from gynecological procedures in which a morcellator was used that was based on the same working principle as tested in-vitro. The instruments used were the Morcellex and the LiNA Xcise (LiNA Medical, Glostrup, Denmark). A data-gathering form, which could be filled in in-tra-operatively by an assistant, was used to collect the necessary morcellator parameters. The laparoscopic videos of the procedures were also obtained (when available) for time-action analysis.

Data collection was thus accomplished with the aid of the data gathering protocol as given in the previous literature research [9]. All data, consisting of patient specific information, morcellator related parameters and time-action analysis data, was analyzed and tested for statistical significance between separate categories with the student’s t-test under the assumption of equal variance. The morcellation rates (IMR, PMR and MCR) as functionality estimates for the working speeds of the instruments are verified through zero-intercept linear regression analysis with accompanying pearson’s correlation coefficient, degrees of freedom and significance values. p-values lower than 0.05 are deemed significant, and all analysis was performed in MATLAB.

**Tissue model**

For ethical reasons, the tissue to be morcellated in the minimal invasive test setup could not be actual human uterine tissue, for which the morcellator is originally intended. For the motor peeling working principle which the Morcellex is based on, the spherical shape of the tissue is key to successful tissue debulking. Therefore, an organ of both roughly equal size and tissue type was needed. The most equivalent animal tissue type to the human uterus is the porcine uterus, but the size and shape of it is not comparable. Where an enlarged human uterus is roughly

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spherical in shape, the porcine uterus is longitudinal and relatively small, making it unfit as a tissue model.

The human uterus mostly consists of smooth muscle cells (myometrium). According to Rorie and Newton [10], the smooth muscle cell concentration in the lower cervix is 6%, 29% in the upper part of the cervix and 69% in the myometrium. This is in accordance with Danforth et al. [11] and Oxlund et al. [12, 13]. The porcine heart, which consists of mostly cardiac muscle, is therefore assumed to be a proper replacement for the uterus with respect to tissue morcellation. Additionally, the heart has a roughly equivalent spherical shape to the enlarged human uterus. To compensate the effect of striations to the cardiac muscle tissue, the Morcelllex is used at the maximum RPM setting (1000 RPM), and the porcine heart is boiled (as suggested by a gynaecologist), which denatures (read: melts) the collagen present in the cardiac muscle tissue. This reduces the toughness of the tissue, and more importantly reduces the effect of striations on the cutting direction, thereby making the porcine heart more comparable to the (approximately homogeneous) uterine tissue. No literature has been found to support this claim, but confirmation of its equivalence was obtained from two experienced gynaecologist.

**Time-action Analysis**

Time-action analysis is a quantitative method that measures the number and duration of the actions needed for an operator to achieve his goal and the efficiency of these actions [14]. This method thus allows for insight into the separate phases which are inherent to the motor peeling working principle. For the purpose of this research, we propose the following phase division:

**Phase 1: Tissue manipulation.** This phase entails engaging and moving the tissue mass in such a way that it is correctly presented to the morcellator dissection method. This phase relies heavily on the skill of the surgeon, as in the case of the standard type of morcellator, the tissue is manipulated with a single grasper disposed through the instrument. The functional-ity of the instrument combined with the skill of the surgeon on how to use it together influence the time and effectiveness of this phase.

**Phase 2: Active morcellation.** Once the tissue is correctly presented to the dissection device, the morcellator is activated to cut the tissue. Simultaneously the surgeon manually transports the tissue through the instrument. The functionality of the instrument combined with the skill of the surgeon on how to use it together influence the time and effectiveness of this phase.

**Phase 3: Tissue deposit time.** The depositing of the tissue is a time-wasting process which, in the current standard morcellation procedure, the surgeon needs to do manually.

By analyzing all video material, measuring the time for each phase per tissue strip removed, and then taking the sum of time spent in each phase, the time-division is obtained.

### RESULTS

The standard operative parameters always reported in literature, i.e. uterine weight, operation time, blood loss, etc., are obtained. Additionally, the morcellation time, the morcellated weight (which is not necessarily equal to uterine weight), the number of tissue strips in which the tissue mass is removed are specified. Also, time-action analysis data is given, allowing insight into the time-division of the separate phases of morcellation both in vitro and in vivo.

**In-vitro obtained morcellation data**

Gathered test data is given in Tab. 2 for both surgeons separately and combined. Due to unavailability of the standard laparoscopic grasper used at hysterectomy procedures (i.e. the krallengreifer), another traumatic grasper was used out of necessity (Endopath 5DSG, Ethicon Endo-surgery) which created some tissue contact issues. Zero-intercept linear regression analysis performed on the morcellated mass versus the removal time, for each surgeon separately, provides an estimate for the reliability of the calculated morcellation rates. The data plotted with the corresponding trend line functions is shown in Fig. 1 and the accompanying trend line functions, including Pearson’s correlation coefficient, degrees of freedom and significance values, are given in Tab. 1. As seen, the obtained morcellation rates are significant.

**TABLE 1. RELIABILITY DATA FOR IN-VITRO MORCELLATION RATES ASSESSMENT.**

<table>
<thead>
<tr>
<th></th>
<th>( Y_i = \beta x_i )</th>
<th>( r )</th>
<th>( df )</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMR Gyn1</td>
<td>( y = 6.71x )</td>
<td>0.9574</td>
<td>3</td>
<td>0.0183</td>
</tr>
<tr>
<td>MCR Gyn1</td>
<td>( y = 31.32x )</td>
<td>0.9492</td>
<td>3</td>
<td>0.0236</td>
</tr>
<tr>
<td>IMR Gyn2</td>
<td>( y = 8.58x )</td>
<td>0.8613</td>
<td>2</td>
<td>0.2321</td>
</tr>
<tr>
<td>MCR Gyn2</td>
<td>( y = 42.11x )</td>
<td>0.2195</td>
<td>2</td>
<td>0.8429</td>
</tr>
</tbody>
</table>

\( df = \) degrees of freedom = \( N - 1 \) for zero-intercept equation
\( p = \) level of significance (two-tailed)

**FIGURE 1. MORCELLATION REMOVAL TIME VERSUS REMOVED WEIGHT, WITH ZERO-INTERCEPT LINEAR REGRESSION ANALYSIS TRENDLINES, \( Y_i = \beta x_i \).**

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TABLE 2. IN-VITRO TEST RESULTS OBTAINED WITH GYNECARE MORCELLEX (N=10), COMBINED AND SEPARATED TO GYNECOLOGIST (WITH LEARNING CURVE REMOVED). DATA PRESENTED AS MEAN±SD(RANGE).

<table>
<thead>
<tr>
<th>Gynaecologist data</th>
<th>Both (n=10)</th>
<th>Gynaecologist 1 (n=4)</th>
<th>Gynaecologist 2 (n=3)</th>
<th>p1/2 *</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time-action analysis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 1: Tissue manipulation (min)</td>
<td>12.0±2.3</td>
<td>(8.3-15.9)</td>
<td>10.0±1.4</td>
<td>(8.3-13.4)</td>
</tr>
<tr>
<td>Phase 1: Tissue manipulation (f1)</td>
<td>0.60±0.04</td>
<td>(0.53-0.66)</td>
<td>0.60±0.05</td>
<td>(0.53-0.63)</td>
</tr>
<tr>
<td>Phase 2: Active manipulation (min)</td>
<td>4.2±0.9</td>
<td>(3.1-6.3)</td>
<td>3.7±0.5</td>
<td>(3.1-6.3)</td>
</tr>
<tr>
<td>Phase 2: Active manipulation (f2)</td>
<td>0.21±0.02</td>
<td>(0.18-0.25)</td>
<td>0.22±0.01</td>
<td>(0.21-0.25)</td>
</tr>
<tr>
<td>Phase 3: Tissue depositing (min)</td>
<td>3.9±1.2</td>
<td>(2.1-5.6)</td>
<td>3.3±1.5</td>
<td>(2.1-5.6)</td>
</tr>
<tr>
<td>Phase 3: Tissue depositing (f1)</td>
<td>0.19±0.04</td>
<td>(0.14-0.27)</td>
<td>0.19±0.05</td>
<td>(0.14-0.27)</td>
</tr>
<tr>
<td>Number of failed cutting attempts</td>
<td>39±24.2</td>
<td>(16-78)</td>
<td>18.5±2.7</td>
<td>(16-22)</td>
</tr>
<tr>
<td>MCR (g/min)</td>
<td>32.2±8.6</td>
<td>(20.5-46.4)</td>
<td>31.4±1.6</td>
<td>(20.5-33.1)</td>
</tr>
</tbody>
</table>

* p1/2 is the significance found between gynaecologist 1 and 2 with the simple student’s t-test; IMR = Instrument Morcellation Rate; MCR = Morcellator Cutting Rate.

TABLE 3. PATIENT CHARACTERISTICS AND OPERATIVE PARAMETERS COLLECTED FROM 18 PATIENTS, WHERE AT 14 PATIENTS TIME-ACTION ANALYSIS WAS PERFORMED. DATA PRESENTED AS MEAN±SD(RANGE).

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>Group 1: &lt;350g</th>
<th>Group 2: 350-749g</th>
<th>Group3: ≥750g</th>
<th>p1/2 *</th>
<th>p2/3</th>
<th>p3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case No. (%):</td>
<td>9 (50%)</td>
<td>7 (39%)</td>
<td>2 (11%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years):</td>
<td>46.1±5.6</td>
<td>(37-55)</td>
<td>45.4±3.7</td>
<td>(41-51)</td>
<td>45.5±0.7</td>
<td>(45-46)</td>
</tr>
<tr>
<td>Gravity:</td>
<td>1.4±1.0</td>
<td>(0.3-3)</td>
<td>2.3±1.7</td>
<td>(1-5)</td>
<td>2.5±0.7</td>
<td>(2-3)</td>
</tr>
<tr>
<td>Parity:</td>
<td>0.8±1.1</td>
<td>(0-3)</td>
<td>1.3±1.3</td>
<td>(0-3)</td>
<td>2±0</td>
<td>(2-2)</td>
</tr>
<tr>
<td>BMI:</td>
<td>24.6±3.5</td>
<td>(19-32)</td>
<td>25.1±5.8</td>
<td>(22-38)</td>
<td>24.1±4.3</td>
<td>(21-27)</td>
</tr>
<tr>
<td>Diagnosis (n (%)):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Uterus myomatus</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Menorrhagia</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operation parameters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uterine weight (g):</td>
<td>152±92</td>
<td>(30-306)</td>
<td>476±1.14</td>
<td>(363-650)</td>
<td>1078±258</td>
<td>(895-1260)</td>
</tr>
<tr>
<td>Morcellated weight (g):</td>
<td>140±74</td>
<td>(30-238)</td>
<td>390±168</td>
<td>(117-650)</td>
<td>1078±258</td>
<td>(895-1260)</td>
</tr>
<tr>
<td>Operation time (min):</td>
<td>149±38</td>
<td>(80-220)</td>
<td>153±54</td>
<td>(105-245)</td>
<td>203±35</td>
<td>(200-205)</td>
</tr>
<tr>
<td>Morcellation time (min):</td>
<td>10.3±5</td>
<td>(3.4-18)</td>
<td>17.4±7.1</td>
<td>(8-29.4)</td>
<td>60±1.1</td>
<td>(59.5-60.9)</td>
</tr>
<tr>
<td>PMR (g/min):</td>
<td>14.3±7.5</td>
<td>(5.8-28.8)</td>
<td>22.6±17.8</td>
<td>(10.6-30.9)</td>
<td>18.0±4.6</td>
<td>(14.7-21.2)</td>
</tr>
<tr>
<td>No. tissue strips (n):</td>
<td>18.1±10.9</td>
<td>(2-38)</td>
<td>35.7±15.1</td>
<td>(16-57)</td>
<td>130±0.7</td>
<td>(130-131)</td>
</tr>
<tr>
<td>Avg. tissue strip weight (g):</td>
<td>9.4±5.2</td>
<td>(2.8-19.8)</td>
<td>10.8±3.1</td>
<td>(7.3-16.8)</td>
<td>8.3±1.9</td>
<td>(6.9-9.6)</td>
</tr>
<tr>
<td>EBL (ml):</td>
<td>331±486</td>
<td>(0-1500)</td>
<td>296±120</td>
<td>(25-800)</td>
<td>150±0</td>
<td>(150-150)</td>
</tr>
<tr>
<td>Excessive bleeding** (n (%)):</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Estimated recovery to ADL (weeks):</td>
<td>3.2±1.7</td>
<td>(2-7)</td>
<td>3.8±1.7</td>
<td>(2-6)</td>
<td>3.5±0</td>
<td>(3.5-3.5)</td>
</tr>
</tbody>
</table>

* p1/2 is the significance found between group x and group y with the simple student’s t-test; ** Blood loss >500ml.
PMR = procedure morcellation rate, MCR = morcellator cutting rate; EBL = Estimated blood loss, ADL = Average Daily Life.
for gynaecologist 1 but not for gynaecologist 2.

Significant differences between surgeons in the time-action analysis are not present, allowing for the combination of all obtained data, and with that gain reliable insight into the time division between the separate morcellation phases. The phases are schematically shown in Fig. 2.

**Clinically obtained morcellation data**

Clinical morcellation data has been obtained from 4 Total Laparoscopic Hysterectomies (TLH), 11 Laparoscopic Supracervical Hysterectomies (LSH) 1 myomectomy and 2 Laparo-Endoscopic Single-Site LSH (LSH-LESS) procedures, divided over 2 gynaecologists, over the course of one year. Two different morcellators have been used, the Gynecare Morcellex (Ethicon, Johnson&Johnson, Amersfoort, Netherlands) and LiNA Xcise (LiNA Medical, Glostrup, Denmark), both relying on the same motor peeling principle. Equal to Chang et al., 2008 [7], the clinically obtained data can be compared to that study (N=10).

Significant differences between surgeons in the time-action analysis are not present, allowing for the combination of all obtained data, and with that gain reliable insight into the time division between the separate morcellation phases. The phases are schematically shown in Fig. 2.

**FIGURE 2.** TIME-ACTION ANALYSIS OF THE TOTAL MORCELLATION PROCEDURE PERFORMED IN-VITRO (N=10).

**FIGURE 3.** MORCELLATION RATES TRENDLINES PMR AND MCR WITH ZERO INTERCEPT FUNCTION \( y_i = \beta x_i \)

**DISCUSSION**

By having used an equal group distribution as Chang et al. [7], the clinically obtained data can be compared to that study.
where they investigated the difference between group 2 and 3. They observed no significant differences in terms of age, body mass index (BMI), preoperative diagnosis, complications and duration of hospital stay. In Table 3 one can see that also here no significant difference is seen with respect to age and BMI between the three groups. Chang et al. further reported an increase in operation time and blood loss with larger uterine size \((p < 0.001)\) between group 2 and 3. As seen in the table, no significant difference in operation time is apparent between groups 1 and 2 \((p_{1/2} = 0.870)\). But the conclusion drawn by Chang et al. is feasible when noting that the significance values \(p_{2/3} = 0.253\) and \(p_{1/3} = 0.090\) for operation time are a lot better compared to \(p_{1/2} = 0.870\). Possibly there is a certain threshold, somewhere around a uterine weight of 750g, after which the operation time starts to increase significantly \((t_{\text{OR}_{\text{gr}1}} = 149 \pm 74\text{min}, t_{\text{OR}_{\text{gr}2}} = 153 \pm 54\text{min}, t_{\text{OR}_{\text{gr}3}} = 203 \pm 3.5\text{min}, \text{explained later in more detail})\). But due to the limited number of samples presented here, this statement cannot be confirmed. Also, a statistically significant increase in blood loss with uterine size is not apparent from the data. Yet a (weak) relation between operation time and blood loss with \(r = 0.43\) and \(p = 0.09\) was found at analysis. Since a significant correlation between uterine weight and morcellation time is present \((r = 0.86, p < 0.001)\), and also the operation time increases with increasing morcellation time \((r = 0.58, p = 0.011)\), it thus stands to reason that given enough datasets a trend between uterine weight and blood loss could emerge.

**Morcellation rates in-vitro and in clinical procedures**

Through analysis, it was observed that both surgeons needed to adjust to the tissue model and the different grasper used in the test setup, suggesting the presence of a learning curve. Both the average tissue strip weight and the calculated Instrument Morcellation Rate (IMR) as a function of trial number for both surgeons are displayed in Fig. 4 and 5 respectively.

Comparing the gynaecologists, after having removed the first and first two trial numbers for the first and second gynaecologist respectively, significant differences are observed for all general morcellation data parameters. Most notable is the statistically significant difference in IMR, showing a slightly faster removal speed of the second surgeon versus the first. Separating the surgeons also proved necessary when comparing the number of failed cutting attempts. Such a failed cutting attempt occurs when the tissue is grasped, and the morcellator is activated while pulling the tissue into the cutting blade, but tissue contact is lost immediately afterwards. This usually happens when the initial contact of the grasper with the tissue is inadequate, but the surgeon attempts to morcellate tissue regardless. Where the first surgeon had a mean of 18.5 failed cutting attempts \((18.5 \pm 2.7)\), the second surgeon had a mean of 62 failed attempts \((62.0 \pm 20.4)\), thus showing that the two gynaecologists manipulate the tissue mass differently.

**FIGURE 4. AVERAGE WEIGHT OF REMOVED TISSUE STRIPS VERSUS TRIAL NUMBER FOR BOTH GYNAECOLOGISTS.**

**FIGURE 5. INSTRUMENT MORCELLATION RATE (IMR) VS. TRIAL NUMBER FOR BOTH GYNAECOLOGISTS.**

Though the second surgeon has a significantly higher number of failed cutting attempts, one must realize that this does not mean that this surgeon is less efficient or skilled in the procedure, because he exhibited a higher IMR and MCR. Nevertheless, this data suggests that, beside the morcellation instrument functionality, there is a difference in the way gynaecologists morcellate, which influences the procedure time and removal speed. As such, when assessing the functionality of a morcellator, the surgeon’s experience needs to be taken into account.

A difference between surgeons in the clinically obtained data has not been observed, which can be explained by the presence of non-linear factors in the actual operating room situation, which are excluded in the in-vitro test setup. These factors include patient variability (parity, gravidity, age, BMI, surgical history, blood loss, etc.) and operating room specific parameters (OR setup, medical staff, etc.). Likely, these extra factors of influence make it impossible to distinguish between surgeons when relatively limited data is available.

Comparing the clinically obtained results to the in-vitro obtained morcellation rates a large difference can be observed. Taking both gynaecologists together, an IMR value of \(6.7 \pm 1.7\) g/min was observed in-vitro for an average removed weight of \(133 \pm 37\) g. Comparing this to the average PMR value for group 1 (with avg. removed weight \(140 \pm 74\) g), \(PMR_{\text{gr}1} = 14.5 \pm 7.5\).
One sees that the morcellation speed obtained in-vitro was approximately half of that found in the operating room. This difference can be accounted for on the basis of various factors. One influence is the difference in tissue model, i.e. the boiled porcine heart vs. a human uterus. A second influence is inherent in that of any surgical test-setup: because no patient is at risk, less pressure for quick and efficient operation is present, and thus it is only natural that the surgeon will have a more relaxed working speed, which translates into a lower PMR value. Lastly, because the standard surgical grasper used at morcellation procedures was not available for testing, another traumatic grasper had to be used. This grasper was less functional for this type of procedure and more prone to prematurely lose its grasp on the tissue mass during morcellation. All these influences combined reduced the in-vitro morcellation speed obtained by an approximate factor of two. Thus all in-vitro morcellation rates observed in literature are likely lower than the actual clinical rates.

Influence of uterine weight

The choice to morcellate depends on various factors, which include the patients medical history, presence of contraindications for vaginal access and surgeon preference and experience. Yet the most important factor taken into account is the uterine weight and size, which influence (or limit) the list of available surgical approaches. Factors correlated with morcellator instrument functionality (PMR, IMR, MCR, \( f \), tissue scatter) have not been defined in literature, and their relations to uterine weight unknown. For that reason, these relations will be analyzed in the following subsections.

Variable morcellation rate

A non-trivial relation exists between PMR and uterine weight. When plotting the uterine weight versus the PMR, Fig. 6 is obtained. Using the full dataset from all the groups combined, trend line \( y_1 \) is created with \( r = 0.42 \) and \( p = 0.087 \), showing a close to, but not fully, significant (weak) relation. But removing group 3 (uterine weight > 750g) from the analysis, trendline \( y_2 \) is obtained with a significantly better and stronger correlation \( (r = 0.69 \& p = 0.003) \). From this relation it can be observed that with increasing uterine weight (within range 0 to 750g), the speed of tissue removal (influenced by both the efficiency of the instrument and the skill of the surgeon) seems to increase. This feels counter-intuitive, because a larger uterus is more difficult to manage due to decreased intra-abdominal movement space, thereby increasing the difficulty of the procedure for the surgeon. But a larger uterus also means that the tissue strips removed during the initial minutes of the morcellation procedure are usually longer and more consistent. When the uterus is large, the instruments peeling principle thus functions optimally, thereby positively influencing the average morcellation rate for that procedure. This is also evidenced by the difference in mean PMR between groups 1 \((14.5 \pm 7.5g/min)\) and 2 \((22.6 \pm 7.8g/min)\).

The above statement can additionally be substantiated with a negative relation found from the time-action analysis, both in-vitro for surgeon 1 and in the clinical data, between morcellator instrument activation time and tissue strip number (in chronological order of removal). Because logically the instrument activation time is correlated with the length of the tissue strip removed at that time, the observed negative relation suggests an optimal peeling effect of the instrument at the beginning of the morcellation procedure, and a decreasing functionality when the tissue mass becomes increasingly distorted. In Fig. 7 the clinical data points are shown together with the clinical trend line and the observed in-vitro relation. The difference in height between the
two trendlines can be explained on the basis of the same issues which influenced the difference in morcellation speed between IMR and PMR (which were: different tissue model and grasper and lack of patient). The negative significant relation observed \( p < 0.001 \) thus explains the relation between PMR and uterine weight, as with larger initial tissue masses the functionality of the instrument increases. And it can therefore be stated that the PMR increases with uterine weight with an estimated cutoff value at an uterus weight around 750g, where the limited intra-abdominal movement space issue takes precedence over the efficiency of the peeling principle of the morcellation instrument.

An important consequence to the observed relation is that based on the uterine weight, the surgeon can make a substantiated decision whether it is beneficial to use a morcellator in the procedure, or that possibly another approach is required. A small uterus (< 150g) has a low removal speed, and might be faster removed through bisection and subsequent vaginal removal than choosing to use a morcellator. A large uterus (> 750g) requires such a long morcellation time when solely morcellating that it might be more beneficial to attempt to only reduce the size of the uterus and subsequently vaginally remove the remainder, thus preferring Laparoscopically Assisted Vaginal Hysterectomy (LA VH) over Total Laparoscopic Hysterectomy (TLH).

**Irrigation and inspection time** The procedure time and speed of removal are not the only important variables to consider when choosing the surgical approach. The number of tissue strips removed, the residual tissue debris (which consists of very small tissue pieces that are removed through inspection and irrigation from the abdomen after the morcellation process has ended), and the recuperation time of the patient need to be taken into account.

Data analysis shows a (trivial) relation between the number of tissue removed and the number of strips in which this is accomplished \( r = 0.94, p < 0.001 \). The same can be stated for the number of tissue strips versus the morcellation time \( r = 0.95, p < 0.001 \), the amount of debris removed versus the total removed weight \( r = 0.83, p < 0.001 \) and the debris versus morcellation time \( r = 0.78, p = 0.001 \). These relations are trivial as more tissue mass removed equals more tissue strips, and thus likely also more residual debris. But the consequence of this increasing number of tissue strips and debris is that by association the time spent by the surgeon checking and irrigating the abdominal area for residual pieces of tissue (which if left behind in the patient could cause inflammation, necrosis and possibly necessitate re-operation) increases. Both the number of tissue strips and debris are significantly positively correlated with irrigation fraction \( f_{irr\&inspec} \) \( r = 0.60, p = 0.032 \) and \( r = 0.71, p = 0.006 \) respectively which is defined as the irrigation and inspection time divided by the total procedure time. Note that \( f_{irr\&inspec} \) is significantly correlated with the inspection and irrigation time with

\[
\begin{align*}
\text{PMR (g/min)} & = 18.693 + 17.477 \times f_{irr\&inspec} \\
(p = 0.00651) & = 0.83
\end{align*}
\]

An increase in \( f_{irr\&inspec} \) thus signifies that the time spent irrigating and inspecting the abdomen for residual tissue debris takes up an increasing amount of time with respect to the total procedure time. Analyzing the relation between \( f_{irr\&inspec} \) and PMR, it is discovered that with increasing PMR, the time spent irrigating increases. This relation is shown in Fig. 8, and would indicate that if the instrument is able to remove the tissue mass faster, it does this at the cost of more tissue spread. Since PMR is also linked to uterine weight, as was shown in figure 6, it appears that the surgeon needs to be able to assess both the irrigation time and morcellation time as a function of uterine weight. For relative large uteri (but < 750g) the morcellator functions optimally in terms of speed, but at the cost of more tissue spread and thus more time spent irrigating the abdomen. The time gained with optimum functioning speed of the instrument might be negated by the increased time spent cleaning afterwards. Moreover, the influence of the number of strips and debris on the patient with respect to recuperation time and re-operation rate is unknown, and is something which should be investigated further in a larger patient-group study.

**Morcellation time vs. irrigation and inspection time**

Though a conclusive analysis of the time gained through optimum function of the instrument versus the time lost due to longer irrigation and inspection time can not be made with this small patient-group study, a reasonable theoretical assessment can be obtained. Taking the relation between \( \text{PMR (g/min)} \) and the morcellated weight \( g \), by defining the linear trend line from the datasets obtained from only groups 1 and 2, gives Eqn. (1). Here the value \( \beta_1 = 0.034 \) (1/min) determines, depending on
the weight of the tissue to be morcellated, the additional morcellation speed, and $\alpha_1 = 9.65$ (g/min) is the minimum PMR rate. Second, obtaining the zero-intercept linear trend line between the morcellation time (min) and the morcellated mass (g) gives Fig. 9 and Eqn. (2). In this function, value 18.7 is equal to the average procedure morcellation rate (g/min) for groups 1 and 2 combined. Realizing that the morcellation rate PMR is dependent on the amount of morcellated mass, and substituting $\text{PMR}(m_{morce})$ (from Eqn. (1)) for $\mu_{PMR}$ (in Eqn. (2)) gives a non-linear approximation for the morcellation time as a function of the weight of the to be morcellated tissue (Eqn. (3)). This trend-line is also displayed in Fig. 9. The non-linear approximation appears to follow the data reasonably well (except for one outlier). Assuming this trend would uphold at a larger patient-study, it shows the increased functionality of the instrument for larger tissue masses, up until a weight of 750g.

Next, the relation between the irrigation time and the morcellation rate for groups 1 and 2 appears to have a very good linear fit in the data ($r = 0.94$ and $p < 0.001$). The relation is given in Eqn. (4). The value 0.032 (min/g) indicates the amount of minutes the irrigation and inspection procedures lasts more per weight of gram of the tissue mass morcellated. In other words, the surgeon adds 1 minute to the irrigation and inspection time for approximately every 30 grams of tissue removed, and has a minimum of 6 minutes of standard checking.

Thus to summarize, there is a non-linear relation between the morcellation time and morcellated weight, and a linear relation between irrigation time and morcellated weight. Rewriting Eqn. (4) to $m_{morce}$, and substituting it into Eqn. (3) gives Eqn. (5); the morcellation time as a function of the inspection and irrigation time. Plotting this function gives Fig. 10.

The relation suggests that the amount of time spent checking the abdomen for debris grows exponentially with the amount of time spent morcellating. Note that this is for tissue masses weighing less than 750g. This relation thus shows that even though there is an increase in morcellator functionality for larger tissue masses, the irrigation time works counter productive to this process. The increased inspection time presumably has a limit at around 30 minutes, because the inspection & irrigation time of group 3 does not scale with this relation, but has an average of 25.4 ± 4.8min.

$$\text{PMR}(m_{morce}) = \beta_1 \cdot m_{morce} + \alpha_1$$  
(1)

$$\beta_1 = 0.034 \left( \frac{1}{\text{min}} \right) , \quad \alpha_1 = 9.65 \left( \frac{g}{\text{min}} \right)$$

$$t_{morce}(m_{morce}) = \frac{m_{morce}}{\mu_{PMR}} , \quad \mu_{PMR} = 18.7 \left( \frac{g}{\text{min}} \right)$$  
(2)

$$t_{morce}(m_{morce}) = \frac{m_{morce}}{\beta_1 \cdot m_{morce} + \alpha_1}$$  
(3)

$$t_{irr}(m_{morce}) = \beta_2 \cdot m_{morce} + \alpha_2$$  
(4)

$$\beta_2 = 0.032 \left( \frac{\text{min}}{g} \right) , \quad \alpha_1 = 6.3 \ (\text{min})$$

$$t_{morce}(t_{irr}) = \frac{t_{irr} - \alpha_2}{(t_{irr} - \alpha_2)\beta_1 + \alpha_1\beta_2}$$  
(5)
The consequence from the relation found in figure 10 is not that the surgeon should choose an optimal amount of tissue to be removed, but to gain insight into the amount of time he or she can expect to be busy with the various parts of the morcellation procedure. With increased uterine weight, the morcellation time increases leading to a significant increase in inspection and irrigation time, resulting in for example such a long procedure time that partial tissue debulking with subsequent vaginal tissue extraction might be quicker and more efficient.

Important is also the insight this relation gains into the morcellators working principle, as an increase in the size of tissue strips removed would be beneficial for PMR. And even though the motor peeling principle functions effectively for large tissue masses, it does this with a large amount of tissue scatter. Thus reducing the amount of debris generated will reduce the amount of time lost due to inspection and irrigation.

### Time-action analysis comparison

As already shown in the results section, the fraction of time spent morcellating the tissue \( f_2 \) increases with uterus size category, and thus with the amount of tissue morcellated. For comparison of the results to the in-vitro data only data of group 1 can be used, because the weight morcellated in the test setup was always below 250g. The separate phases are displayed for comparison in Tab. 4.

The fraction of time spent morcellating in the test setup is approximately equal to the actual operating room setting. The tissue manipulation phase is significantly longer in the test setup, which can be accounted to the different traumatic grasper which had to be used. This grasper thus introduced a disadvantageous artifact to the test data. Furthermore, the time spent depositing tissue in the test setup is significantly less than the actual situation, which can easily be explained: in the test setup a small collection cup stood directly beside the surgeon, allowing the depositing of tissue with minimal effort. In the actual setting the surgeon depends on his surgical team in order to deposit the tissue. Due to the relatively cluttered environment a cup can usually not simply be placed in front of the surgeon, thus an assistant presents this cup whenever it is necessary. This logically takes more time. Moreover, the grasper sometimes needs to be cleaned by an assistant, which was never done in the tests, thus saving more time. Moreover, the grasper also needs to be cleaned by an assistant, which was never done in the tests, thus saving more time.

### Table 4. Comparison time-action analysis test setup versus OR-data

<table>
<thead>
<tr>
<th></th>
<th>Test setup</th>
<th>OR data</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>( f_1 )</td>
<td>0.60±0.04</td>
<td>0.52±0.08</td>
<td>0.011</td>
</tr>
<tr>
<td>( f_2 )</td>
<td>0.21±0.02</td>
<td>0.20±0.04</td>
<td>0.444</td>
</tr>
<tr>
<td>( f_3 )</td>
<td>0.19±0.04</td>
<td>0.29±0.07</td>
<td>0.003</td>
</tr>
</tbody>
</table>

The consequence from the relation found in figure 10 is not that the surgeon should choose an optimal amount of tissue to be removed, but to gain insight into the amount of time he or she can expect to be busy with the various parts of the morcellation procedure. With increased uterine weight, the morcellation time increases leading to a significant increase in inspection and irrigation time, resulting in for example such a long procedure time that partial tissue debulking with subsequent vaginal tissue extraction might be quicker and more efficient.

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### Table 5. Comparison morcellation rates between test setup and operating room data

<table>
<thead>
<tr>
<th></th>
<th>IMR (g/min)</th>
<th>MCR (g/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>test setup</td>
<td>6.7±1.7</td>
<td>32.2±8.6</td>
</tr>
<tr>
<td>PMR (g/min)</td>
<td>7.5±1.7</td>
<td>71.7±34.4</td>
</tr>
</tbody>
</table>

\[ MCR = \frac{M_{more}}{t_{more}}, \text{ with } t_{phase1} = t_{more} \text{ phase 1} \quad \text{and} \quad t_{phase2} = t_{more} \text{ phase 2} \]  \( \text{(6)} \)

spent in this phase. This speed would then be more specific to the cutting ability of the morcellator. The morcellator cutting rate (MCR) has already been given in Tab. 2 and Tab. 3 and is defined as Eqn. (6).

In Tab. 5, the MCR values for both the test setup and the OR data are displayed for comparison to the PMR and IMR values. As is seen, the difference between test setup and the actual operating room situation is still very distinctive, which is caused by the difference in total morcellation time. This makes an effective speed comparison between the test setup and the actual situation only possible if an approximate factor 2 is taken into account when working with a boiled porcine heart as a tissue model.

### Conclusion

Data on the functionality of the Gynecare Morcelllex tissue peeling morcellator was acquired both in-vitro, with the use of a boiled porcine heart as tissue model, and in the operating room during normal morcellation procedures. Significant results were obtained with zero-intercept linear regression analysis between the weight of the morcellated tissue and the morcellation time, suggesting that the tissue removal rates can be used to effectively asses the combined functioning speed of the instrument and the surgeons skill. Large differences were observed in-vitro between surgeons. Due to significant uterine weight variability observed in-vivo, the OR-dataset was split into three groups based on uterine weight. Significant differences between the groups were found at operative time, morcellation time, procedure morcellation rate (PMR), number of tissue strips removed...
and irrigation and inspection time. A positive morcellation rate dependence with uterine weight was observed, showing that the efficiency of the morcellator tissue peeling principle relies on the initial size and shape of the uterus. For larger uteri, the PMR increases, which led to a non-linear morcellation time estimation. Furthermore, a linear relation was observed between morcellated weight and irrigation and inspection time (for the removal of tissue debris), showing that with more removed weight the time spent on cleaning the intra-abdominal area increases. The time gain obtained through optimum functioning of the morcellator with increased uterine weight is counteracted by the increasing irrigation and inspection time. On the basis of pre-operatively estimated uterine weight, the surgeon is able to use these relations to obtain a better estimate of the consequences for procedure time and tissue spread when opting for the use of a morcellator.

Time-action analysis provided insight into the time spent manipulating tissue (phase 1), effectively morcellating (phase 2) and depositing tissue (phase 3), which are inherent phases in the tissue peeling morcellation principle. Significant equivalence of phase 2 between the test setup and the operating room situation was obtained, showing the laparoscopic box setup to be an efficient evaluation tool for assessing the time-distribution of a morcellator. Instrument morcellation rates (IMR) obtained from the test setup were approximately half of those obtained from actual procedures (PMR), which can be explained on the basis of the tissue model and limitations in the test setup. Great scope for improvement of the procedure and instrument is apparent from the high observed downtime (80%) which if lowered can lead to an increase in PMR, reduce the number of actions a surgeon needs to perform, and potentially lower the procedure duration. Furthermore, improving or changing the dissection method to decrease the amount of debris created will lead to a reduction in the inspection and irrigation time.

ACKNOWLEDGMENT

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THE DESIGN, PROTOTYPING AND EVALUATION OF A TRANS-VAGINAL MORCELLATOR FOR TOTAL LAPAROSCOPIC HYSTERECTOMY

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ABSTRACT

Various morcellators for use during total laparoscopic hysterectomy (TLH) are available on the market. These function through one of the minimal incision sites created during minimally invasive surgery, and allow the surgeon to efficiently remove the partially or fully resected uterus from the intra-abdominal area. Due to the inherent limitations in removing tissue through a small tube of approximately 12 mm, this process takes a long time as relatively small pieces of tissue are repetitively removed from the main tissue mass. Moreover, the process is associated with large tissue spread which leads to a long inspection and irrigation phase for the removal of tissue debris. In order to address these issues, this article describes the design, prototyping and proof-of-principle evaluation of a novel trans-vaginal morcellator for TLH which, when developed further, will remove larger tissue pieces and function faster with less tissue spread, compared to the current standard morcellators, to reduce the overall procedure time. The instrument includes a rotationally vibrating sharp circular cutting blade as dissection method, which is slanted to allow for trans-vaginal morcellation under an angle. Together with an outer passive tube, the morcellator allows for tissue peeling with reduced tissue scatter. A larger functional tube dimensions compared to standard instruments ensures thicker tissue strip creation and a mechanism was implemented to allow for adjustability in the amount of cutting blade exposure.

NOMENCLATURE

IMR Instrument Morcellation Rate (g/min). Morcellator functioning speed determined from in-vitro obtained data.

PMR Procedure Morcellation Rate (g/min). Morcellator functioning speed determined from data collected at hysterectomy procedures involving morcellation.

MCR Morcellator Cutting Rate (g/min). Effective morcellator cutting speed determined by excluding tissue manipulation and depositing phases in the morcellation process.

f time found for a specific time-action analysis phase (1-3) divided by morcellation time.

INTRODUCTION

Relatively little data with respect to the functionality of specific morcellator working principles is present in literature. To assess the various morcellators available on the marked, a literature study [1] was performed, where key conclusions were:

1. The working principle named ‘motor peeling’ is currently the fastest available on the market (utilized in the following instruments; Gynecare Morsellex, Storz Rotocut G1, Wolf Morce Power Plus, LiNA Xsice).
2. The size of the incision influences the morcellation rate. A larger incision allows for the application of a morcellator with an equally sized tube diameter (available=10, 12 and 20mm) to remove thicker tissue pieces leading to an increased morcellation speed.
3. The continuity of a morcellation process should be optimized and the number of actions a surgeon needs to perform to morcellate be reduced.

These four statements lead to the preliminary conclusion that an optimally designed morcellator needs to have a continuous working principle and allow optimal control over the tissue mass whilst having a large functional diameter but simultaneously minimizing impact on the patient. Even though most technological advances in MIS instruments are aimed at increasingly smaller and thinner instruments, the exact opposite is needed for the morcellator from a functionality point of view. Creating a morcellator as described above would in theory function faster than motor peeling morcellators but not necessarily safer. That is because there are still certain problems associated with the currently available morcellators applied through a minimal incision. These include significantly increased procedure time, unwanted tissue spread in the abdominal cavity (potentially causing inflammation and/or necrosis [2–5] ) and increased inspection and irritation time for removal of tissue debris [6]. These issues negatively influence the duration, difficulty and safety of the procedure.

The goal of this article is to detail the design and development of a novel morcellator which takes into account the above statements and issues. The morcellator is designed to be used during a Total Laparoscopic Hysterectomy (TLH) procedure (field of gynaecology) where an enlarge uterus is resected and fully removed. In standard practice the removal process is accomplished by (partially or fully) morcellating the uterus through one of the minimal incisions. In this procedure, due to the full resection of the uterus (including cervix), the vaginal canal is available for easy access to the abdominal area. Partial debulking of the uterus with a morcellator and subsequent trans-vaginal removal of the remaining tissue mass is a therefore a frequently applied method. But often the vaginal cuff is first sutured closed before continuing on with the tissue removal process, and thus all tissue removed through an abdominally applied morcellator.

Currently no morcellators exist making optimal use of the trans-vaginal canal, created during TLH and similar laparoscopic full uterus removal procedures, to access the abdominal cavity. But a trans-vaginal morcellator allows for a larger functional allowed diameter when using the vaginal canal and thus has the potential for the removal of larger debulked tissue strips. Moreover, the lowest pocket in the abdominal area (called the recto-uterine pouch or cul-de-sac) is the location where the resected uterus would lie stable at rest (due to gravity). And the trans-vaginal approach directly access this location and would thus allow the surgeon more control over the tissue mass during morcellation as it is supported at this location. Moreover the use of the vaginal canal has a minimum impact on the patient. In Fig. 1 a comparison is given between the standard MIS approach and a hypothetical trans-vaginal morcellation approach.

FIGURE 1. SCHEMATIC REPRESENTATION OF STANDARD MORCELLATION APPROACH VS. THEORETICAL TRANS-VAGINAL MORCELLATION AT TLH. PICTURE OBTAINED AND ALTERED FROM PASIC AND LEVINE, 2007, P.300 [7].

From the above observations the following hypothesis was derived for TLH procedures:

“A transvaginal morcellator can have a large functional diameter and safely be applied in a Total Laparoscopically Hysterectomy (TLH) leading to a reduction in procedure time compared to abdominally applied motor peeling morcellators.”

Through evaluation of the speed and functionality of a morcellator relying on the electromechanical peeling principle [6] it was observed that in order to speed up the morcellation process the removed tissue strips should be longer and thicker, reducing the amount of tissue strips created during the procedure. This then will reduce the time lost during tissue manipulation and depositing phases, effectively lowering the instrument downtime of 80% and increasing the average Procedure Morcellation Rate (PMR, g/min). Increasing the tissue strip size necessitates a larger functional morcellation tube diameter, hence the hypothesized superiority of a trans-vaginal morcellator which allows for the use of larger morcellator dimensions (compared to those applied through MIS incisions, ±35mm vs. 10mm) without in-
creasing the impact of the procedure on the patient.

To summarize, this article proposes a trans-vaginal morcellator as solution to the problems which accompany the use of the standard minimally invasive morcellation approach. The designing process, prototyping stage and evaluation of a the instrument is discussed in subsequent sections.

CONCEPTUAL DESIGN

In this section the criteria which a novel morcellator should satisfy, the designing process and the final design are described.

Criteria

The design of a novel trans-vaginal morcellator is subject to various criteria. Firstly, it must (logically) function through the vaginal canal, even when contraindications are present. Contraindications for vaginal hysterectomy include a uterine weight > 280g (12 weeks of gestation) [8, 9], adnexal masses, the need for salpingo oophorectomy, previous pelvic surgery, lack of uterine accessibility and mobility, or severe pelvic disease [10]. By estimation, the diameter of the morcellation tube should not exceed 35mm.

Secondly, the instrument should allow for the complete removal of uterine sizes which are impossible to be removed intact through standard Vaginal Hysterectomy (VH). The instrument must also debulk and remove tissue at a rate on par with the most widely used morcellation working principle; i.e. the motor peeling principle. According to literature [1], the procedure morcellation rate (PMR) of motor peeling morcellators ranges between 25 and 40g/min. Through research the morcellation rate was found to be dependent on uterine weight though [6], thus a new instrument should operate at a PMR value at optimum functioning. Supposing a uterus weight of 750g, using the function found from trend analysis in this research, this would equal\[1\]
\[
PMR = 35g/min.
\]
Because PMR can only be determined in clinical practice, for the purpose of evaluation, the minimum Instrument Morcellation Rate (IMR) (which was also determined in the same study) needs to be \( IMR_{35g} = 6.5g/min \) when testing in-vitro on a boiled porcine heart. Similarly, the in-vitro Morcellation Cutting Rate (MCR) obtained through time-action analysis should at least be \( MCR_{35g} = 32g/min \).

Independent of the tissue dissection and removal method chosen in the design of a new morcellator, the tissue needs to remain histologically interpretable. According to Landman et al. (2000) [11], tissue pieces of 3g a piece (obtained with the Steiner ‘motor coring’ morcellator) were suitable in size for both grading and possible staging of renal tumors. Additionally, from clinical research an approximate average tissue strip weight of 9.8g is found to be the current standard size submitted for evaluation [6]. A novel instrument is thus allowed to remove the tissue mass in smaller tissue strips than the standard morcellators provide, but never below 3g per piece.

The downtime in a morcellation process is the amount of time spent neither debulking nor transporting tissue, and thus basically wasted time from an optimization point of view. This can happen when a process is for example discontinuous, as with ‘motor peeling’ morcellators where debulked tissue strips need to be pulled out of the morcellator and disposed in a container with a grasper before reinserting the grasper for re-engaging the main tissue mass and continuation of the morcellation process. This downtime needs to be kept as low as possible to ensure optimal use of procedure time. For that reason the maximum allowed downtime is 80%, as given by Arkenbout et al. [6], of the total morcellation time (which is far from optimal), and should preferably be less.

Any time gained through optimization of the morcellation process (by reducing %-downtime) should not be lost due to increased intra-abdominal inspection and irrigation time (i.e. the spent looking and removing residual debris generated by the morcellator). Thus time-gain of the morcellator can also be accomplished through reduction of the amount of debris generated. The minimum inspection and irrigation time as a fraction of the total procedure time is found to be in the range of 0.07 to 0.13 [6], which should not be exceeded.

Lastly, the instrument should be able to function in a forced pneumoperitoneum, and be used safely. In literature there is a general consensus when using a ‘motor peeling’ morcellator to never advance it into the abdominal cavity (because moving around inside the abdomen with an aggressive dissection method is dangerous), but rather draw the tissue to the cutting blade [12]. Additionally, the surgeons needs to be able to directly see the debulking process in order to ensure safe morcellation.

Designing process

The designing of a novel morcellator is accomplished through the use of a problem decomposition scheme [13]. Two types of decomposition schemes are used in conjunction with each other to generate a final scheme, from which subsequently brainstorming trees for every defined component were created. The first decomposition scheme is functional decomposition, which is the division of the main instrument goal(s) into smaller sub-functions which are solved individually and then combined and/or merged to obtain a final product. The second scheme is the decomposition by sequence of the user actions, where an instrument is separated into the different user tasks which need to be performed. First the functional decomposition, given as a black-box in Fig. 2, is expanded to give all objective components, and the energy-, material- and signal-paths combining them. Subsequently color coding the separate subtasks to their respective morcellation phases (which are the surgeon tasks), gives one better insight into how the user is affected by the dif-

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1\( PMR_{(m_{source})} = 0.034 \cdot 750 + 9.65 = 35.15g/min \), see Eqn. (1) in article [6]

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ferent morcellator subtasks. Fig. 3 shows the end result.

![Blk box representation of funtion decomposition](Image 47x624 to 273x699)

**FIGURE 2.** BLACK BOX REPRESENTATION OF FUNCTION DECOMPOSITION

The separate morcellator phases (i.e. the color coding) are taken from the time-action analysis phase division as defined by Arkenbout et al., 2012 [6]. These are:

**Phase 1: Tissue manipulation.** This phase entails engaging and moving the tissue mass in such a way that it is correctly presented to the morcellator dissection method. This phase relies heavily on the skill of the surgeon, as in the case of the standard type of morcellator, the tissue is manipulated with a single grasper disposed through the morcellator.

**Phase 2: Active morcellation.** Once the tissue is correctly presented to the dissection device, the morcellator is activated to cut the tissue. Simultaneously the surgeon manually transports the tissue through the instrument. The functionality of the instrument combined with the skill of the surgeon on how to use it together influence the time and effectiveness of this phase.

**Phase 3: Tissue deposit time.** The depositing of the tissue is a time-wasting process which, in the current standard morcellation procedure, the surgeon needs to do manually.

With the problem decomposition scheme presented in Fig. 3 both the separate components which make up the morcellator and the user influence (i.e. the surgeon’s skill) can be analyzed. There are four inputs: two separate energy sources, one activation signal, and a force. All these inputs combine to achieve externalized morcellated tissue as an output, which is then deposited to allow the process to start anew. The first energy input is stored and/or accepted and transmitted to a component which translates the energy into dissection energy. This dissection action is activated through a signal (second input) being transmitted through a trigger tool operated by the surgeon. The third input, the force, is applied to the tissue mass in order to eventually engage the tissue mass with the dissection method. The result of the first and third input paths combine eventually to apply the dissection energy to the tissue mass. While cutting tissue, it is necessary to translate the tissue out of the body either simultaneously or after all the tissue has been cut. This could be accomplished with the already applied force (input 3), but also through some other means of automatic transportation. Thus a fourth input channel is added to again store and/or accept energy, translate this into translational energy and apply this to the tissue mass which is being dissected. The result is a loop or a one-time interaction between cutting the tissue and translating it through/past the dissection method. The end result is externalized morcellated tissue, in any size or shape, which subsequently is deposited.

Now looking at the standard morcellation procedure (as tested in [6]), and color coding it to the separate phases, one sees a clear time distribution. First the surgeon engages and manipulates the tissue (third input path; blue), then activates the morcellator (first and second input paths; red) and dissects the tissue while transporting it away (fourth input path; blue, and internal loop; red&blue). Finally the tissue is externalized and deposited (external loop; green). The blue components heavily rely on the user, and the red components are mainly mechanical components of the instrument.

For each separate component of the problem decomposition a brainstorm tree has been created. The separate items, which are A) dissection method; B) trigger tool; C) tissue manipulation; D) dissected tissue translation; E) energy sources and F) deposit morcellated tissue, will not be discussed here in depth. Combination of brainstorm options from each item led to several concepts. The primary design choices relate to the dissection method (A) and the dissected tissue translation (D), and the found solutions for the remainder of the separate decomposition items follow as best fit options. For more information into the various dissection methods available in medical practice, one can refer to a literature study performed by v.d. Berg, 2010 [14].

**Final design**

In Fig. 4, 5 and 6 the 3D model of the final design is shown. As specified at the criteria section, the design has a larger tube diameter compared to the standard abdominally applied morcellators (30 vs. 12). The design is based on a rapid rotationally vibrating cutting blade, because it is assumed that this dissection method creates less tissue debris with respect to the rotating cutting blade used in standard practice. Because a rapid rotating blade spins the tissue mass at times due to friction, causing aggressive tissue spread, a vibrating blade, which does not have this friction-issue, should theoretically reduce the amount of debris scatter. The vibrational motion is achieved through the use of an electric motor transferring its rotational motions to a swivel-arm rigidly connected to an inner tube with the cutting blade at its distal end. The cutting principle relies on the same tissue peeling principle as the current standard, but with the main difference that it achieves this trans-vaginally (with a larger tube diameter). This allows the tissue strips which are peeled off the tissue mass to be larger, thicker, and less prone to prematurely tear off the main tissue mass, making the peeling method more reliable and thus potentially limit the amount of tissue scatter. The distal tip
of the inner cutting tube with the passive peeling-enabling outer tube is displayed in Fig. 5.

The cutting blade is activated when the surgeon pulls back the trigger which is rigidly connected to the outer tube of the instrument. Pulling the trigger thus slides the outer tube backwards, thereby exposing the cutting blade to a certain (adjustable) degree and simultaneously activating the electric motor with a trigger mounted in the instrument (not shown in the SolidWorks model). The electric motor is connected through an adapter to an external power outlet.

In order to achieve some degree of adjustability in setting the maximum allowable cutting edge as shown in Fig. 5, a mechanism is implemented, manually tunable, which changes the maximum allowable outer tube translation. This is schematically displayed in Fig. 6. Being able to set the amount of blade exposure is a novel option which allows the surgeon to control the amount of cutting blade exposure. Because the power of the electric motor is equally distributed over the entire length of the functional cutting edge, reducing the length of the exposed blade theoretically increases the force applied to the tissue per millimeter length of the functional cutting edge (in F/mm). This can aid the surgeon in dissecting tougher tissue such as myomas.

The tissue is engaged and removed through the use of a grasper, identical to the standard method used in practice. The
DIMENSIONAL DESIGN

This section describes the calculations performed for the inner vibration-enabling mechanism and insight into the cutting blade geometry.

Vibrational mechanism calculations

In order to efficiently cut tissue, the necessary torque to be delivered by the electric motor in a worst-case-scenario needs to be calculated in order to assure that the cutting blade will not stall. Suppose a load of 30N is applied tangential to the cutting blade, the stall torque can then be defined as \( T_{\text{stall}} = F_{\text{max}} r \), where \( r \) is the moment arm equal to half the cutting blade diameter and \( F_{\text{max}} \) the maximum allowable force applied to the blade. In Fig. 7, this is schematically displayed. The motion described by the electric motor, and the transfer of this rotary motion into an angular vibration is shown in Fig. 8. A pin, placed off-center relative to the rotational axis of the electric motor, is rotated, and pushes a swiveling arm alternating left and right while translating up and down in a groove.

The load \( F_{\text{max}} \) needs to be overcome by the electric motor. But it should be taken into account that due to the motion conversion, the torque applied by the electric motor is not always fully utilized. As is displayed in Fig. 8, the force generated by the torque of the motor is always tangential to the circular motion. In order to calculate the effective force with which the electric motor pushes the swivel arm left and right, first an angle, \( \beta \), between the force, \( F_{\text{max}} \), and the centerline of the swiveling arm needs to be determined as a function of the rotation \( \gamma \) of the motor. In order to find this, first the angle \( \alpha \), which is the rotation angle of the cutting blade, needs to be stated as a function of \( \gamma \). This is:

\[
\alpha(\gamma) = A(\gamma) \arctan \left( \frac{L_2}{L_1} \right), \quad \text{where} \quad A(\gamma) = \frac{v_{\text{vertical}}}{v_\perp} \quad (1)
\]

where \( L_1 \) is the distance between the axis of the blade and the electric motor, and \( L_2 \) is the distance between the off-center pin and the axis of the electric motor (see Fig. 7 and 8). \( v_\perp \) is the tangential speed of the off-center pin equal to \( r \omega \), where \( r \) is the radius equal to \( L_2 \), and \( \omega \) is the angular velocity (rad/s). \( v_{\text{vertical}} \) is the vertical component of the tangential speed vector, and thus \( A(\gamma) \) is the normalized vertical speed profile of the off-center pin, ranging between 1 and -1. Simplifying this gives \( A(\gamma) = \sin(\gamma) \), whereby follows:

\[
\alpha(\gamma) = \sin(\gamma) \arctan \left( \frac{L_2}{L_1} \right) \quad (2)
\]

Now that \( \alpha(\gamma) \) is know, \( \beta(\gamma) \), the angle between \( F_{\text{max}} \) and the centerline of the swivel arm, can be defined:

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FIGURE 7. SCHEMATIC REPRESENTATION OF A WORST-CASE LOAD APPLIED TO THE CUTTING BLADE, $F_{MAX} = 30$ N.

FIGURE 8. VIBRATION MECHANISM: A ROTATIONAL MOTION, DELIVERED BY ELECTRIC MOTOR FORCE $F_m$, RESOLVED INTO VECTORS $F_{m\perp}$ AND $F_{m\parallel}$, VARYING WITH MOTOR ANGLE $\gamma$, WITH RESPECT TO THE SWIVELARM, IS TRANSLATED INTO AN ANGULAR VIBRATION $\alpha$.

FIGURE 9. TORQUE GENERATED BY THE ELECTRIC MOTOR THROUGH THE SWIVEL ARM TO THE CUTTING BLADE VS. WORST-CASE-SCENARIO STALL TORQUE.

\[ \beta(\gamma) = 90 - (\gamma - \alpha(\gamma)) \]  

(3)

With angle $\beta(\gamma)$, the force $F_m$ can be decomposed into the forces perpendicular, $F_{m\perp}$, and parallel, $F_{m\parallel}$, to the centerline of the swivel arm. By multiplying $F_{m\perp}$ with the length of the moment arm $L(\gamma)$, from the point of contact of the off-center pin to the center axis of the cutting blade, the torque generated by the electric motor to the cutting blade through the swivel arm can be determined. Thus:

\[ F_{m\perp}(\gamma) = F_m \sin(\beta(\gamma)) = \frac{T_{motor}}{L_2} \sin(\beta(\gamma)) \]  

(4)

and

\[ L(\gamma) = \sqrt{(L_2 \sin(\gamma))^2 + (L_1 + L_2 \cos(\gamma))^2} \]  

(5)

can be combined into:

\[ T(\gamma) = F_{m\perp}(\gamma)L(\gamma) \]  

(6)

where $T_{motor}$ is the torque generated by the electric motor. Using the parameters as indicated in Table 1, a plot for the torque is given for one motor revolution in Figure 9.

| TABLE 1. CHOSEN PARAMETERS TO PREVENT WORST-CASE-SCENARIO STALL LOAD. |
|---|---|---|---|
| Parameter | Value | Parameter | Value |
| $L_1$ | 62 mm | $F_{max}$ | 30 N |
| $L_2$ | 7.5 to 15 mm | $P_{motor}$ | 36 W |
| $\beta_{blades}$ | 28 mm | Motor speed | 3700 RPM |

Cutting blade geometry

The cutting blade is slanted under an angle of 45 degrees and the distal end of the outer passive tube is also slanted but under a slightly different angle. Additionally, the outer tube is allowed to slide with respect to the inner tube with the blade at its distal tip. Translating the outer tube thus allows for full, partial or zero exposure of the cutting blade, as shown in Fig. 6.

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This blade is also placed under an angle because of its intra-abdominal location. When trans-vaginally positioning the morcellator, the cutting blade is automatically located at the bottom of abdomen, at the recto-uterine pouch (see Fig. 1). Because of the angle under which the morcellator will enter the abdominal space, it is dangerous to have a cutting blade equal in geometry to the standard morcellators, as it would cut straight down into the large intestines. Placing this blade under an angle is thus a necessity for the safety of the patient, and allows for safe morcellation under an angle.

PROTOTYPE

The full instrument, with and without its casing, is shown in figure 10. The mechanism to set the amount of exposure of the cutting blade as shown in the SolidWorks model in Fig. 5 is implemented in this prototype. This amount of blade exposure can be adjusted by twisting a knob at the back of the instruments, which rotates a threaded axle. On this axle a blocking plate is mounted which can be moved forward or backwards depending on the rotation direction of the knob. By twisting this knob, the user can thus translate the plate to any desired location, as schematically shown in the previous section (Fig. 6). This location directly determines the amount of maximum translation possible of the outer tube and the finger trigger pin, and thereby thus also the maximum allowable exposure of the cutting blade. By pushing the trigger pin backwards, the outer tube is slid backwards and the pulse switch triggered (small red knob). This activates the motor which makes the cutting blade vibrate. Releasing the trigger pin allows the internal spring to slide back the outer tube, thereby covering the cutting blade and disconnecting the power supply to the motor. This mechanism thus simultaneously acts as a safeguard because the blade can only be active as long as the surgeon is actively keeping the trigger pin pushed back. Moreover, the surgeon intuitively knows the amount of exposure of the cutting blade, because the distance which the trigger pin travels upon morcellator activation is directly equal to the amount of blade exposure.

EVALUATION

The prototype is evaluated in an identical minimal invasive test setup as discussed by Arkenbout et al., 2012 [6]. This test setup includes a minimally invasive boxtrainer with two lateral and two median trocar entry points and a laparoscope and screen. In order to simulate the vaginal access point in this setup, the novel morcellator will not be inserted through one of the trocar ports, but from the side. An experienced gynaecologist, assisted by a surgeon in training, morcellated one boiled porcine heart with the novel instrument. Due to limitations in the setup, tissue model, and the amount of time available, no additional tests could be performed.

The instrument is assessed on the basis of the data gathering protocol proposed by Arkenbout et al., 2011 [15], and compared to the Gynecare Morcellex tested in the same test setup [6]. Additionally a time-action analysis is performed. Note that the total evaluation is a proof-of-principle assessment, and not a statistical comparison to other morcellators.

RESULTS

All gathered data is presented in Tab. 2. For comparison purposes, the data obtained from the Gynecare Morcellex [6], has also been added to the table.

At the test, the novel morcellator removed 113g out of 347g in 20.5 minutes leading to an instrument morcellation rate of $IMR_{\text{prototype}} = 5.5g/min$. Comparing this to the value obtain in-vitro with the Morcellex, $IMR_{\text{morcellex}} = 6.7 \pm 1.7g/min$, it is seen that the morcellator is almost on par with this standard instrument. The average tissue strip weight measured in-vitro at the Morcellex furthermore was $2.4 \pm 0.6g$. Testing the prototype, approximately 22 tissue strips (including small debris pieces) were removed, giving an average of $5.1g$ per piece, showing the positive effect of being able to use a morcellation tube with a larger diameter. Note that this average tissue strip weight is also beneficial for histological evaluation.

With only one porcine heart morcellated, a comparison of the time-action analysis when using the prototype with the previously acquired Morcellex test data will not be fully reliable. Even so, the obtained data from this analysis is shown in Tab. 2, and the piecharts of the analysis versus the found results for standard tissue peeling morcellators from the morcellator functionality study [6] are shown in Fig. 11.
TABLE 2. COMPARISON TABLE TEST RESULTS IN-VITRO PORCINE HEART MORCELLATION WITH GYNECARE MORCELLEX AND PROTOTYPE.

<table>
<thead>
<tr>
<th>Morcellation data:</th>
<th>Morcellex test</th>
<th>Prototype</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total morcellation time [min]</td>
<td>0:20:10±0:03:41</td>
<td>0:20:28</td>
</tr>
<tr>
<td>Total tissue mass [g]</td>
<td>409±82</td>
<td>347</td>
</tr>
<tr>
<td>Tissue mass morcellated [g]</td>
<td>133±37</td>
<td>113</td>
</tr>
<tr>
<td>IMR* [g/min]</td>
<td>6.7±1.7</td>
<td>5.5</td>
</tr>
<tr>
<td>MCR* [g/min]</td>
<td>32.2±8.6</td>
<td>20.6</td>
</tr>
<tr>
<td>Number of removed tissue strips</td>
<td>56±12.7</td>
<td>22</td>
</tr>
<tr>
<td>Avg. weight tissue strips [g]</td>
<td>2.4±0.6</td>
<td>5.1</td>
</tr>
<tr>
<td>Number of failed cutting attempts</td>
<td>39±24</td>
<td>18</td>
</tr>
</tbody>
</table>

Time-action analysis:

| Tissue manipulation time [f]         | 0:12:02±0:02:17        | 0:12:14          |
| Tissue manipulation time [f]         | 0.60±0.04              | 0.60             |
| Morcellation blade active [f]        | 0:04:13±0:00:54        | 0:05:29          |
| Morcellation blade active [f]        | 0.21±0.02              | 0.27             |
| Tissue deposit time [f]              | 0:03:56±0:01:09        | 0:02:45          |
| Tissue deposit time [f]              | 0.19±0.04              | 0.13             |

*IMR = Instrument Morcellation Rate; MCR = Morcellator Cutting Rate.

FIGURE 11. TIME-ACTION ANALYSIS COMPARISON OF IN-VITRO DATA WITH THE PROTOTYPE (LEFT) VS. THE MORCELLEX (RIGHT).

DISCUSSION

This section discusses the limitations which were inherent in the test setup, followed by a comparison between the prototype and the Gynecare Morcellex. Next a small section is dedicated to discuss what changes for the standard Total Laparoscopic Hysterectomy when using a trans-vaginal hysterectomy. And finally future prototype development and accompanying safety aspects are discussed.

Limitations in the test setup

Upon attempting to morcellate the boiled porcine heart it was found that due to the difficult to fabricate blade geometry, the sharpness of the blade was not on par with that of standard morcellators. Even though the blade was special made for this purpose, it dulled quickly upon use and was difficult to sharpen. Additionally, the grip on the tissue needed to be adequate to allow for enough force generation of the tissue against the blade. Due to the used tissue model, frequent loss of contact of the grasper with the tissue was present, making efficient morcellation difficult. This limitation of the tissue model was also apparent in the study performed to assess the Gynecare Morcellex functionality [6].

Though the setup accurately simulates the median and lateral ports used during minimal invasive procedures, it did not have a simulated vaginal access point. In order to simulate the trans-vaginal approach the new prototype is supposed to take, the surgeon could not use any of the trocar ports, but instead applied the morcellator from the side (the test box did not have any side walls). The problem which followed was that the surgeon intuitively moved the morcellator with the image he saw on the video screen in order to maneuver the instrument with respect to the tissue mass. This is an automatic response, but one which is impossible at an actual procedure, since the instrument is confined by the trans-vaginal canal through which it is disposed. These movements of the instrument should thus be avoided in the test setup by simulating the vaginal canal, and thereby confining the instrument to one position. Furthermore, the tissue mass was located in a relatively deep tray in the setup. When vaginally applying a morcellator, it will enter the abdomen from the bottom, at the cul-de-sac. As a result, when morcellating tissue, the tissue mass will lie at the bottom of the abdominal space, and thus lie stable. Because of the deep tray, the morcellator could not be used easily at the bottom, but instead had to be (aggressively) angled downwards to the bottom to reach the tissue mass. Or alternatively the tissue mass needed to be pulled upwards towards the cutting blade, which created additional contact issues between the tissue and the grasper.

Lastly, the standard camera angle was insufficient to allow the surgeon constant vision on the morcellation blade. When grasping the tissue, the mass was kept sideways to allow the surgeon to maneuver the laparoscopic grasper. Once a firm grip was obtained, the tissue mass was pulled against the blade, effectively blocking the surgeons vision. Though the morcellator only starts cutting when the surgeon pulls the trigger, which translates the protective blade cover backwards and activates the blade, it is important to make sure that no other tissue structures are accidentally cut. With a standard laparoscope this can only be done by first making sure that the distal tip of the morcellator is clear of all structures before engaging it with the tissue mass. Alternatively a laparoscope with an angled 30-, 45-, or 135-degree lens or a flexible laparoscope could be used to obtain vision on the blade while morcellating. Another issue which presented itself was the inherent difficulty in working with a grasper which is inserted opposite of the camera angle, i.e. going left on screen is going right in reality and visa versa. And though the surgeon is experienced in minimally invasive procedures, this is counterintuitive, making tissue manipulation more difficult.
Comparison prototype vs. standard

Comparing the results with the Morcellex data [6] shows that based on the IMR value, the novel prototype is slightly slower. This is due to the limitations discussed in the previous section. But because of the increased allowed diameter of the morcellation tube, the average tissue strip size is larger, showing potential for a higher morcellation rate should the dissection method itself become more efficient. Noting that at the in-vitro assessment of the Morcellex [6] a learning curve was apparent where the IMR values were lower at the first and second morcellation tests, it is possible that in the same way the test performed here with the prototype was subject to a learning curve. Thus the speed found could possibly exceed the Morcellex when performing more tests.

Comparing the time-action analysis data it can be seen that the tissue manipulation time fractions are roughly equal ($f_1 = \frac{1}{0.60}$. The active morcellation fraction ($f_2$) in the prototype is higher and the amount of tissue strips created lower, showing that the instrument was activated less frequent but for longer periods of time to obtain larger tissue strips. This then explains the reduced amount of time spent depositing the tissue because fewer tissue strips need to be disposed off. When viewing the morcellator cutting rate (MCR), it is seen that the Morcellex is still faster ($MCR_{morcell} = 32.2 \pm 8.6g/min$ vs. $MCR_{prototype} = 20.6g/min$), due to the lower cutting capacity on account of the (by comparison) blunt cutting blade of the prototype. With a sharper cutting blade, and a better ergonomic design, allowing the surgeon more intuitive and easier instrument handling, it can be expected that the tissue manipulation time will decrease in favor of the morcellation time, and faster morcellation with fewer and larger tissue strips should result.

Surgical procedure changes

In total laparoscopic hysterectomy, after the uterus has been resected from its surroundings, and the uterus mobilizer removed (an instrument used to move the uterus when required during the hysterectomy procedure), the vaginal cuff is sutured closed before starting the tissue morcellation process. Closing the vaginal cuff right after amputation is done in order to prevent unnecessary blood loss and more easily uphold the pneumoperitoneal pressure. However, it is not a necessity to close it straight away, so long as any bleeders are coagulated and the abdominal pressure is upheld (by placing for example a surgical glove with a sponge inside in the vagina as suggested by Pasic and Levine, 2007 [7], p.206).

Using a trans-vaginal morcellator necessitates keeping the vaginal cuff open after uterine amputation, and inserting the morcellator (with an obturator) to uphold the pressure. Insertion of the rigid morcellator itself should not be an issue because a McCartney Tube, which is a single use plastic transvaginal tube, is also a rigid instrument which is frequently applied. It is used (among other things) for anatomical structure identification, upholding the pressure and providing a conduit for introduction of the needle and suture used for closing the vaginal cuff [16]. Because the current morcellator design uses a diameter of 30mm, and the McCartney tube is available is sizes 35 and 45mm, it is even possible to use the new morcellator through a McCartney tube.

After the tissue mass is morcellated with this prototype, the instrument needs to be removed, and the vaginal cuff sutured closed. Because the morcellation tube is fully hollow it allows for the introduction of the needle and suture. Furthermore, the trans-vaginal morcellator in the final design has to have a pressure seal incorporated in it to uphold the abdominal pressure while in use. And thus when closing the vaginal cuff, it might not even be necessary to remove the instrument. Instead one can partially retract the morcellator and keep it in place until the cuff is fully sutured closed, before removing it fully.

Though designed for use during total laparoscopic hysterectomy, the morcellator could potentially also be used during supraservical procedures, where the cervix stays intact. Through a (relatively large) culdotomy or colpotomy incision the instrument can still gain access to the abdominal area. The instrument needs to be advanced sufficiently into the abdomen then to prevent the blade from hitting the cervix.

Future prototype development and safety

A final design of the trans-vaginal morcellator needs to have a pressure seal incorporated in it. This seal can be applied at the proximal end of the morcellation tube (equal to the current standard morcellators). The vibrational mechanism also needs to be optimized to reduce friction between the swivel arm and the rotating axle which transfers the motor rotations. Moreover, the electric motor could also be removed from the design, and be replaced by an external one. The Gynecare Morcellex makes use of a generator which transfers the rotation of an electric motor through a flexible drive cable to the instrument and the cutting blade. A similar system could be used, or the morcellator designed to function with an already existing external motor, such as the Gynecare Morcellex motor drive unit MD0100 (Amersfoort, Netherlands).

With respect to safety, certain anatomical structures around the vagina need to be protected when morcellating. The bladder and the large intestines are located above and below the uterus respectively, and accidentally cutting these will severely complicate the procedure. In order to protect these structures, some form of a barrier could be placed between the structures and the morcellator. Note that this barrier does not need to push back tissue or apply any significant force to any of the tissue structures. It merely needs to be present between the morcellator and its surroundings in order to prevent tissue from accidental slipping in between the blade and the resected uterus when morcel-
lating. Thus the barrier is allowed to be relatively flexible. For this purpose nitinol wires are perfectly suited. Nitinol (NiTi) is a shape memory and superelastic alloy with biocompatible properties [17–20], which is already being used in biomedical instruments (such as self-deploying endoscopic bags). Because of its properties, Nitinol can be created to deploy into any shape, and as such, nitinol spring wires are an excellent method of deploying a barrier from a small tube into a large pre-defined shape. The addition of an elastic sheet material (such as the material from which endoscopic bags are made) will provide one with a deployable barrier which can protect the bladder and the large intestines from touching the morcellator blade. The surgeon only needs to steer clear of the small intestines (as is standard practice). A simple schematic representation of the morcellator with the incorporation of these wires is shown in Fig. 12. This barrier will not only protect the surrounding structures, but will also function as a funnel for the tissue mass and tissue debris. Any debris created due to the morcellation process (which, due to the vibrating blade dissection method, should be less than the standard morcellator) will be funneled to the tip of the morcellator due to the barrier. Thus theoretically, any tissue debris will be more easily removed.

CONCLUSION

This article proposed a novel strategy for Total Laparoscopic Hysterectomy and presented the designing, prototyping and proof-of-principle evaluation of a novel trans-vaginal morcellator. Through the use of ‘function decomposition’ and ‘decomposition by sequence of the user actions’ the actions which a morcellator must accomplish and the user interaction was identified. Brainstorm trees for every objective item of the decomposition scheme allowed for the generation of numerous concepts, which were iteratively revised to finally reach one single design to be prototyped. The dissection method chosen is a rotationally vibrating sharp circular cutting blade which is slanted to allow for trans-vaginal application. Together with an outer passive tube, the morcellator allows for tissue peeling with reduced tissue scatter. A mechanism was added to allow for adjustability in the amount of cutting blade exposure.

The prototype was evaluated in a minimally invasive test setup and was found to have an almost equal speed to the standard motor peeling Gynecare Morcellex. It produced larger and fewer tissue strips, leading to a decreased tissue depositing fraction and an increased active morcellation fraction compared to the Morcelex. Increasing the effectiveness of the morcellation blade, which was difficult to fabricate and relatively blunt compared to the standard morcellator blades, is believed to allow for quicker and more efficient morcellation than the current standard. Suggestions for safety improvements have been made, including nitinol wire guided expanding barriers to protect tissue structures around the vaginal cuff from touching the morcellation blade.

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